Section IV - 4c

Example 3

Appendix A - Statement of Work

APPENDIX A

STATEMENT OF WORK

BETWEEN

[NAVY COLLABORATOR]

And

[NON-NAVY COLLABORATOR]

[Navy Collaborator] will be responsible for the following tasks (list as applicable):

1. This institution acknowledges and accepts responsibilities for protecting the rights and welfare of all human subjects involved in the research which it sponsors or conducts and will follow all pertinent regulations (FDA, OPRR, DoD, and others) when involved in such research. This institution encourages and promotes an institutional atmosphere that safeguards the rights and welfare of human subjects. This institution will conduct annual protocol reviews and submit reports to the oversight committee as required in the pertinent regulations.

2. The investigator will process each protocol through the Institutional Review Board (IRB) at **[Navy Collaborator]**. In addition, comply with local, state, and federal regulations while conducting the research.

3. Review each protocol provided by **[Non-Navy Collaborator]**. The Investigator to let **[Non-Navy Collaborator]** know if **[Navy Collaborator]** will participate in a specific protocol.

4. The Investigator will follow each protocol and amendments as describe. Any variation will be provided to the **[Non-Navy Collaborator]** Protocol Coordinator and **[Navy Collaborator]** IRB.

5. Administrative duties will be performed as required by the protocol; reporting, charting of patient participation, obtaining appropriate consent forms, and other duties as described in the protocol.

6. **[Non-Navy Collaborator]** Protocol Coordinator will have access to patient charts. Documentation will be available during EVMS inspection.

[Non-Navy Collaborator] will be responsible for the following tasks (list as applicable):

1. Supply each complete protocol and/or amendment to the Investigator at **[Navy Collaborator]** for review. Each protocol will format and information will comply with Navy regulations.

2. The Project Administrator is responsible for data management, preparing reports as requested by **[Navy Collaborator]**, documenting adverse reactions in a timely manner.

3. Chart reviews to be completed to verify pertinent pre-entry examinations. Verify dates of therapy, administration of subsequent doses, and ensure appropriate methods were followed.

4. Verify adherence of protocols. If a protocol deviation occurs, ensure accurate documentation of deviation.

5. Ensure adverse drug reactions are appropriately reported.

6. Verify patient disease status and document. Ensure adequacy of follow-up exams.

7. Drug accountability records. The Protocol Coordinator shall ensure accurate drug inventory at all times. In addition, the Protocol Coordinator will supply drugs as listed in each protocol. Ensure accountability and participant records are accurate.

[Navy Collaborator] and [Non-Navy Collaborator] will be responsible for the following joint tasks:

1. Each facility will ensure annual continuing reviews are conducted through each IRB. Informed consent is approved each year.